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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/574,816	04/06/2006	Rui Yuge	20060477A	3663

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EXAMINER	
KIM, TAEYOON	

ART UNIT	PAPER NUMBER
1651	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/574,816	YUGE ET AL.	
	Examiner	Art Unit	
	Taeyoon Kim	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 December 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *46-48,50-53,55,56 and 59-62* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *46-48,50-53,55,56 and 59-62* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/17/2008 has been entered.

The advisory action mailed on 12/23/2008 is withdrawn due to the filing of RCE on 12/17/2008.

Response to Amendment

Applicant's amendment and response filed on 11/21/2008 has been received and entered into the case.

Claims 1-45, 49, 54, 57, 58 and 63 are canceled, and claims 46-48, 50-53, 55, 56, 59-62 have been considered on the merits. All arguments have been fully considered.

The objection to the specification has been withdrawn due to the amendment.

The claim objection has been withdrawn due to the amendment.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

> invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 46-48, 50-53, 55, 56, 59-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pickhard (of record) in view of Dow Corning article (of record) and Codner (of record) in further view of Baidwan et al. (of record), Karakashian (of record) and Polak (of record).

Pickhard teaches a syringe device having a housing (main body), slidable plunger (a volume varying means), a frontal end region (discharge part; a mouth part) linked an injection needle, a deformable ampoule (a contractible bag-type vessel) having a concertina section (see part #14 of Fig. 1 and 11), which can be ruptured (opened) by a piercing device (part #30 of Fig. 11). Pickhard also teaches the material for the deformable ampoule being pharmaceutical rubber or silicone (see column 8, lines 15-21). Since silicone is well known in the art as a gas permeable material as supported by the Dow Corning article (see the Table of Permeability rate of silicone rubber).

Although Pickhard does not teach the intended use of the device to hold handling medium containing cells, the silicone vessel (ampoule) of Pickhard is considered to be suitable for cell culturing. This is because Codner teaches a bag-like vessel made of gas-permeable silicone membranes is suitable for cell culture (see abstract). Thus, the silicone ampoule of Pickhard would be considered to be capable for cell culturing as claimed invention.

With regard to the limitation of oxygen permeability, since plastic is well known in the art to be oxygen permeable, the examiner takes the position that the plastic material

used in Pickhard would have inherently met the limitation of quantity of the gas permeability in terms of overall oxygen permeability claimed in the instant invention.

The Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether or not applicants' gas permeable material differs, and if so to what extent, from the plastic material (a gas permeable resin) discussed in Pickhard. Accordingly, it has been established that the prior art material demonstrates a reasonable probability that it is either identical or sufficiently similar to the claimed material for gas permeability region that whatever differences exist are not patentably significant. Therefore, the burden of establishing novelty or unobviousness by objective evidence is shifted to applicants.

Merely because a characteristic of a known plastic material is not disclosed in a reference does not make the known plastic material patentable. The new material possesses inherent characteristics which might not be displayed in the tests used the reference. Clear evidence that the plastic of the cited prior art do not possess a critical characteristic that is possessed by the claimed gas permeable resin, would advance prosecution and might permit allowance of claims to applicants' device.

Pickhard does not teach the gas permeable region being formed at a tip of the plunger.

Baidwan et al. teach a vented piston (see Abstract and Fig.1).

It would therefore have been obvious for the person of ordinary skill in the art at the time the invention was made to use the piston of Baidwan et al. in the syringe device of Pickhard.

The skilled artisan would have been motivated to make such a modification because the vented piston of Baidwan et al. is to exhaust the air while pushing the piston, and it is considered the same purpose as the gas permeable region on the main body (barrel) taught by Karakashian. Thus, a person of ordinary skill in the art would be motivated to use the vented piston of Baidwan et al. to further facilitate pressure equalization to relieve back pressure with reasonable expectation of success.

Since the gas permeable region formed at the tip of the plunger of Baidwan et al. is for the same purpose as the gas permeable region of Polak, it would have been obvious to combine these two components for the syringe of Pickhard in view of Dow Corning article, in further view of Karakashian and Polak.

M.P.E.P. §2144.06 states "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re* Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be prima facie obvious.). See also *In re* Crockett, 279 F.2d 274, 126 USPQ 186 (CCPA 1960) (Claims directed to a method and material for treating cast iron using a mixture comprising calcium carbide and magnesium oxide were held unpatentable over prior art disclosures that the aforementioned components individually promote the formation of a nodular structure in cast iron.); and *Ex parte* Quadranti, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992)

(mixture of two known herbicides held prima facie obvious).

Pickhard is silent of the gas permeable region on a main body extending in a sliding direction of plunger.

Karakashian teaches that a barrel of a syringe device is made of plastic, which is inherently gas permeable (see column 3, lines 44-51).

It would therefore have been obvious for the person of ordinary skill in the art at the time the invention was made to make the syringe device of Packard having a main body (barrel) being gas permeable.

The skilled artisan would have been motivated to make such a modification because Karakashian teaches that having the barrel gas-permeable, it would be efficient to sterilize the device by gas sterilization to prevent contamination. Such modification would inherently meet the limitation of intended use of the device in cell handling.

The person of ordinary skill in the art would have had a reasonable expectation of success in making the main body or barrel of Pickhard's syringe device to be gas permeable.

Furthermore, it is noted that it is extremely well known in the art that majority of syringe device is made of plastic and thus gas permeable. Therefore, it would have been obvious to person of ordinary skill in the art to try to make the barrel of Pickhard's device with plastic resin because there are a finite number of gas permeable material available for making a syringe barrel, and plastic material or plastic resin is common material known in the art for such purpose.

The Supreme Court recently states in KSR v. Teleflex (550 US82 USPQ2d 1385, 2007) "The same constricted analysis led the Court of Appeals to conclude, in error, that a patent claim cannot be proved obvious merely by showing that the combination of elements was "obvious to try." Id., at 289 (internal quotation marks omitted). When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under §103."

With regard to the modification to the mouth (discharge part) of the vessel being covered with a closing member, it is well known in the art that any syringe type device would be capable of being connected to other conduit or a catheter, and using a cap to close the opening at the end of the discharge part. In fact, Pickhard discloses a coupling component communicating with hypodermic needle by way of flexible tubing (catheter or conduit) (see column 16, lines 23-26). Furthermore, Polak teaches a fitted cap to close the opening at the end of the syringe barrel (see column 11, lines 12-14; and Fig. 5, #127).

With regard to the limitations that the multiple locations of gas permeable region on the main body which extends in a sliding direction of the plunger and the gas permeable region having higher gas permeability than the principal material of the main body, the teaching of Karakashian indicates that the whole main body is made of plastic

and therefore considered to have gas permeable region at a sliding direction of the plunger.

However, Pickhard in view of Karakashian do not teach differential permeability of the gas permeable region and the main body.

Polak teaches a syringe barrel having a region (a hole) made of gas permeable membrane (see Fig. 7-9), which is a liquid-impervious and gas permeable semi-permeable membrane (see column 7, lines 4-26), and therefore it is considered to be porous film and apparently having higher gas permeability than the plastic material of Karakashian.

Therefore, it would have been obvious to a person of ordinary skill in the art to use the barrel of Polak's syringe in the syringe device of Pickhard in view of Karakashian. This is because the syringe of Polak is considered as an art-accepted equivalent to the Karakashian. Furthermore, the gas-permeable membrane of Polak provides pressure equalization and thereby relieves the back pressure, while maintaining a sterile environment in syringe assembly (see column 11, lines 55-63).

With regard to the newly introduced limitation drawn to the main body including a gas permeable region comprising a porous film made of one of more of polytetrafluoroethylene, tetrafluoroethylene-hexafluoropropylene copolymer (Teflon), polyethylene terephthalate, polypropylene, polyethylene or hydrophobic polyvinylidenefluoride, Polak teaches polypropylene is suitable semi permeable membrane (liquid impermeable/gas permeable) to be used for the hole (gas permeable region) on the syringe barrel (col. 7, lines 4-26). Furthermore, since the fluororesin

species of disclosed in the claims are well known in the art for the gas-permeable materials, it would have been obvious to a person of ordinary skill in the art to substitute polypropylene of Polak with other semi permeable (gas permeable/liquid impermeable) materials such as fluororesins.

Although Polak does not particularly teach the shape of the hole having gas permeable membrane extending in a sliding direction of the plunger, it would have been obvious to a person of ordinary skill in the art to try various different shapes or number of holes made in the main body.

With regard to shape change, M.P.E.P. §2144.04 states "In re Dailey, 357 F.2d 669, 149 USPQ 47 (CCPA 1966) (The court held that the configuration of the claimed disposable plastic nursing container was a matter of choice which a person of ordinary skill in the art would have found obvious absent persuasive evidence that the particular configuration of the claimed container was significant.)."

Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill at the time the invention was made.

Response to Arguments

In the response to the previous office action, applicant argued that the silicone vessel or ampoule of Pickhard is not suitable for holding a fluid handling medium that contains cells because the material used in Pickhard for part #17 is resiliently deformable plastic, silicone and the like, while part #18 is made from a more stable and rigid plastic PVC or similar material.

It is not clear how applicant concluded that the Pickhard ampoule/injection device is not suitable for hoding a fluid handling medium that contains cells. This argument is not persuasive since there is no evidence provided that the vessel or ampoule device of Pickhard is not suitable for the cell and handling medium. The argument presented in the reponse is mainly the argument of counsel and is unsupported by evidence or declarations of those skilled in the art. Attorney argument is not evidence unless it is an admission, in which case, an examiner may use the admission in making a rejection. See M.P.E.P. § 716.01(c) for examples of attorney statements that are not evidence and that must be supported by an appropriate affidavit or declaration.

With regard to the argument based on the new limitation drawn to a gas permeable region on the main body, applicant alleged that the gas permeability level of a silicone resin is far less in comparison to the materials for a gas permeable region on the main body. This might be correct. However, applicant compares two different parts of the device. The silicone material of interest is for the ampoule (vessel) holding a fluid handling medium containing cells inside a main body (syringe barrel), whereas the porous films with listed species of fluororesins and/or polypropylene, etc. are for forming a gas permeable region on the main body. The silicone resin is not for main barrel of syringe of Pickhard, rather it is for the ampoule inside of the main body. Thus, the argument based on the silicone resin being used for the gas permeable region of the main body is not persuasive.

Furthermore, since Polak teaches a main syringe body comprising a hole (gas permeable region) made of polypropylene, the references teach the limitation of the

current invention. Thus, this argument is not persuasive to overcome the claim rejection.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taeyoon Kim whose telephone number is (571)272-9041. The examiner can normally be reached on 8:00 am - 4:00 pm ET (Mon-Thu).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Taeyoon Kim/
Examiner, Art Unit 1651